

REMARKS

Response to §112 Enablement Rejection

In response to the Examiner's final rejection of claims 1 and 13 under 35 U.S.C. §112, first paragraph for alleged lack of enablement, Applicants have hereby cancelled claims 1 and 13.

Response to §103 Obviousness Rejection

In the outstanding Office Action, the Examiner rejected claims 25 and 26 under 35 U.S.C. §103(a) for alleged obviousness over European Patent Application Publication No. 0565010 A1 filed in the name of Antonio Rizzo (hereinafter "Rizzo"). Specifically, the Examiner asserted that Rizzo discloses the use of creatine phosphate for stimulating hair growth and that because creatine is the free, non-phosphorylated form of creatine phosphate and is structurally similar to creatine phosphate, it would be obvious to one of ordinary skill in the art to use creatine for stimulating hair growth as well as stimulating DNA synthesis in dermal papilla cells (see Office Action, page 7, lines 7-18).

However, it is important to note that claims 25 and 26 of the present application do not recite just the general use of creatine for stimulating hair growth and DNA synthesis in dermal papilla cells. Instead, claims 25 and 26 recite the use of creatine within a very specific molar concentration range, namely, "from about 0.25mM to about 1mM," for achieving hair growth stimulation and DNA synthesis stimulation in dermal papilla cells. For example, Examples 1 and 2 of the present application prove, with actual experimental data, that creatine at very low molar concentrations (e.g., 1 mM or less) is nevertheless effective in increasing hair

growth in hair plugs as well as DNA synthesis in dermal papilla cells by statistically significant levels in comparison with untreated controls.

The cited reference Rizzo discloses a composition containing the combination of levodopa, phosphate creatine, ursodeoxycholic acid, and L-ascorbic acid for stimulating new hair growth, reinvigorating existing hair, preventing hair from turning grey, and promoting hair repigmentation (see Rizzo, column 3, lines 23-30). D1 specifically discloses a lotion for topical use that contains, per each 100 ml of lotion, about 2500 mg of levodopa and about 500 mg of phosphate creatine (see Rizzo, column 3, liens 48-50), which if converted into molar concentration is about 23.68 mM of phosphate creatine (which has a molecular weight of about 211.11 g/mole). Further, Rizzo suggests that different doses of phosphate creatine may be used and that it may vary from 10% to 30% of the quantity of levodopa, which in turn may vary from 1,500 to 4,500 mg in the 100 ml lotion (see Rizzo, column 4, lines 1-8). In other words, the amount of phosphate creatine in the 100 ml lotion may vary from 150 mg to 1,350 mg, which if converted into molar concentration is from about 7.1 mM to about 63.9 mM of phosphate creatine.

In contrast, the pending claims of the present application recite a composition containing creatine at significantly lower molar concentrations, i.e., from about 0.25 mM to 1 mM.

Even if assuming arguendo that a person ordinarily skilled in the art would have been motivated to use creatine instead of phosphate creatine, following the Examiner's assertion (despite lack of any such suggestion by Rizzo), the molar concentration of creatine used would be comparable to that of phosphate creatine and would also be from about 7.1 mM to about 63.9 mM, because 1 mole of creatine can be phosphorylated into 1 mole of phosphate creatine. Therefore, it is clear that the Rizzo reference fails to teach or suggestion or even appreciate the

capability of creatine in effecting hair growth and DNA synthesis in dermal papilla cells at molar concentrations as low as that recited by the pending claims 25 and 26 of the present application.

Further, the cited reference Rizzo only vaguely states that application of the lotion described therein achieved “extremely favourable results” when tested in persons afflicted with different pathologies varying from simple hair loss to androgenic alopecia (see Rizzo, column 4, lines 26-32), but failed to provide any quantitative experimental data to support such a vague conclusive statement.

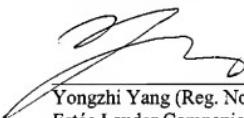
In contrast, the present application provides detailed quantitative data to show that creatine is effective in increasing DNA synthesis of Normal Human Dermal Papilla (NHDP) cells by 36%, 25% and 6% respectively at concentrations of 0.25 mM, 0.5 mM and 1 mM (see Example 1 of the instant specification on pages 7-8). Further, the present application provides experimental data to show that 1 mM of creatine is effective in increasing hair growth in hair plugs by nearly two folds in comparison with the untreated hair plugs (see Example 2 of the instant specification on pages 9-10).

Therefore, unlike the Rizzo reference, which provides merely a vague conclusive statement without any quantitative supporting data, the present application demonstrates the effectiveness of creatine in promoting DNA synthesis of NHDP cells and hair growth in hair plugs with convincing experimental data.

Based on the foregoing, Applicants submit that pending claims 25 and 26 of the present application are both novel and inventive over the cited reference Rizzo by positively reciting a composition comprising creatine in an amount ranging from about 0.25 mM to 1 mM.

Correspondingly, all pending claims of the present application are in condition for allowance, and the Examiner is thereby requested to issue a Notice of Allowance in Applicants' favor.

Respectfully submitted,



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